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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,478	03/04/2002	Jin Jen	126881201800	1461

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,478

Applicant(s)

JEN ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-11 and 14-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20010427.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The election with traverse filed July 7, 2004 is acknowledged and has been entered.

In accordance with the restriction and election requirement set forth in the Office action mailed April 7, 2004, Applicant has elected the invention of Group VI, claims 1, 3, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed PGP9.5 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

2. Claims 1-30 are pending in the application. Claims 2, 4-11, and 14-30 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 7, 2004.

3. Claims 1, 3, 12, and 13, drawn to the elected invention, are currently under prosecution.

Election/Restrictions

4. Applicant has traversed the restriction and election requirement set forth in the Office action mailed April 7, 2004, arguing that the requirement is improper because the Office failed to properly apply restriction practice under PCT Rules 13.1 and 13.2 with respect to the Markush groups in claims 1, 14, and 30. Briefly, Applicant has argued that there is unity of invention, since the requirement for a technical relationship involving one or more special technical features is met by the independent claims, since the alternative embodiments recited in those Markush-type claims are of similar nature.

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Applicant's arguments traversing the restriction and election requirement set forth in the previous Office action mailed April 7, 2004 have been carefully considered but not found persuasive for the following reasons:

MPEP § 1850 [R-2] states "lack of unity may exist within a single claim". § 1850 [R-2] further states:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

Defining "alternatives of a similar nature", § 1850 [R-2] states the alternatives within a single claim must have (a) a common property or activity and (b) a common substantial structure or in the absence of a common substantial structure, belong to a recognized class of chemical compounds, "mean[ing] that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention".

Applicant has argued that the alternative embodiments of claim 1, for example, are each methods for diagnosing a neoplasm of the lung comprising detecting the presence of a proto-oncogene, wherein said proto-oncogene is selected from a group of alternative proto-oncogenes commonly associated with lung cancer cells by their overexpression. Applicant has accordingly argued that the requirement of a technical interrelationship and the same or corresponding "special technical feature", as defined by PCT Rule 13.1, should be considered met, since the alternative proto-oncogenes are of "alternatives of a similar nature" because each has a common property (i.e., an association with lung cancer).

However, as noted above, "alternatives of a similar nature" must also have a common substantial structure or, in the absence of a common substantial structure, belong to a recognized class of chemical compounds. The alternative proto-oncogenes do not share a common substantial structure, since each comprises a unique polynucleotide sequence and encodes a functionally and structurally distinct protein.

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While each of recited alternative proto-oncogenes belong to a recognized class of chemical compounds, i.e., nucleic acids, because any other member of this class of chemical compounds could not be substituted for those members recited in the claim with the expectation that the same intended result would be achieved, the recited alternatives are not "alternatives of a similar nature".

Arguendo, if the recited alternatives were recognized as belonging to a class of chemical compounds, which, in particular, function as proto-oncogenes, because any other proto-oncogene could not be substituted for those members recited in the claim with the expectation that the same intended result would be achieved, the recited alternatives could still not be regarded as "alternatives of a similar nature". Many proto-oncogenes are not associated with lung cancer.

In further reply to Applicant's argument, then, that the special technical feature of the alternative embodiments of claim 1, for example, is detecting the presence of a proto-oncogene associated with lung cancer by its overexpression to aid in the diagnosis of a neoplasm of the lung, as defined by PCT Rule 13.2, the expression "special technical feature" shall mean "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art". The prior art teaches that detecting proto-oncogenes, which are associated with lung cancer by their overexpression, can be used to aid in the diagnosis of lung cancer. For example, Hojo et al. (*Respir Med.* 1998 Feb; **92** (2): 184-190) teaches the mutated p53 gene is detected in a variety of human cancers, including lung cancer, and is considered as an oncogene; see, e.g., the abstract. Therefore, the same or corresponding technical relationship among the alternative embodiments of claim 1 to which Applicant has pointed does not define a significant contribution over the prior art, and is therefore not properly considered a "special technical feature".

Moreover, as evidenced by the rejections of the instant claims under 35 USC §§ 102 and/or 103 below, to the extent that the claim 1, for example, is drawn to the elected invention, the prior art teaches that detecting the gene encoding PGP9.5, which are associated with lung cancer by its overexpression in lung cancer cells, is used to aid in the diagnosis of lung cancer. Therefore, again, the same or corresponding technical

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relationship among the alternative embodiments of claim 1 to which Applicant has pointed cannot be regarded as a "special technical feature", as defined by PCT Rule 13.2.

For the same or analogous reasons, the alternative embodiments of claims 14 and 30 are not "alternatives of a similar nature"; nor do they share the same or corresponding technical feature that defines a significant contribution over the prior art with regard to their novelty or inventive step.

Accordingly, the restriction and election requirement set forth in the previous Office action is deemed proper and therefore made FINAL.

Information Disclosure Statement

5. The information disclosure filed April 24, 2001 has been considered. An initialed copy is enclosed.

Oath/Declaration

6. The declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-dated alterations have been made. See 37 CFR § 1.52(c).

Specification

7. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark includes GenBank™ (page 31, line 7).

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Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., TM, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

Claim Objections

8. Claims 1, 12, and 13 are objected to because claim 1 is drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

9. Claim 12 is objected to because of the following informality: "Presence" is misspelled as "presenece" in line 1 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because the claim recites, "the lung cancer". The limitation finds no antecedent basis in either of claims 1 or 12. Although claim 1 recites, "the neoplastic condition of a lung cell", this recitation does not provide antecedent basis for the recitation, "the lung cancer" in claim 13, since, in particular, the terms are not of commensurate scope. Amending claim 12 to recite, for example, "wherein said neoplastic condition of a lung cell is non-small lung cancer" can obviate this ground of rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mooi et al. (*Histopathology*. 1988 Sep; **13** (3): 329-337), as evidenced by Wilkinson et al. (*Science*. 1989 Nov 3; **246** (4930): 670-673) (of record; cited by Applicant).

Claims 1, 3, 12, and 13 are drawn to a method for aiding in the diagnosis of a neoplasm of the lung, or more particularly, non-small cell lung cancer, comprising detecting the presence of PGP9.5 in a lung cell sample.

Mooi et al. teaches a method for aiding in the diagnosis of primary lung carcinomas, including, in particular, non-small cell lung cancer, comprising detecting the presence of the protein gene product 9.5 (PGP9.5) in lung cell samples; see entire document (e.g., the abstract; page 332, paragraph 2; page 334, paragraph 2; page 336, paragraph 2).

Mooi et al. does not explicitly teach the gene encoding PGP9.5 is "overexpressed" or that its overexpression is indicative of lung cancer. Nevertheless, Mooi et al. does teach the presence of PGP9.5 in lung cell samples is indicative of lung cancer, and, as evidenced by Wilkinson et al., for example, the gene is normally only expressed in select neurons and ganglia (see entire document; e.g., the paragraph bridging pages 671 and 672). Thus, due to its lack of normal expression in the lung, where the gene is abnormally expressed in the lung cancer cells, it is overexpressed those cells.

Conclusion

14. No claims are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 13, 2004